

Atty. Docket No. 414176

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### REMARKS

The remarks presented herein attend to all outstanding issues in the pending Office Action of March 28, 2006. Claims 1-28 are pending.

Claims 1, 18, 21 and 25 have been amended to recite *at least one dielectric element disposed along at least a portion of the distal ends of the conducting elements ... to electrically insulate the cornea from the electrical conducting elements*. Support for this amendment may be found, for example, in paragraphs [0022], [0040], [0043], [0045], [0054] and [0057] – [0059]; and FIGS. 3 and 5-8 of the application. The dependency of claim 17 has been amended. Claim 19 has been amended to conform to the new language of claim 18, and claim 20 has been amended to provide proper antecedent basis for the element comprising anodized aluminum. No new matter has been added to the claims by these amendments.

### Claim Objections

Claim 17 is objected to under 37 CFR § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 17 has been amended to recite “The applicator of claim 16”, and should now be in proper dependent form. Reconsideration of claim 17 is requested.

### Claim Rejections – 35 U.S.C. § 102

Claims 1 and 3 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Applicant's Admitted Prior Art (AAPA) shown in Figure 1 of the instant application. Respectfully we disagree.

To anticipate a claim, a reference must teach every element of the claim and “the identical invention must be shown in as complete detail as contained in the... claim.” *MPEP 2131* citing *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 2

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USPQ2d 1051 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989).

AAPA fails to anticipate independent claim 1 because it does not teach or even suggest an applicator for performing thermokeratoplasty having at least one thermally conductive dielectric element disposed along at least a portion of the distal ends of the conducting elements ... to electrically insulate the cornea from the electrical conducting elements, as required by claim 1. As shown in Fig. 1 of the present application, AAPA includes a flow gap 114 that prevents the thermally conductive dielectric element from being disposed along at least a portion of the distal ends of the conducting elements. Accordingly, independent claim 1, as well as claims 2-17 which depend directly or indirectly therefrom, distinguish over AAPA and represent allowable subject matter.

#### Claim Rejections – 35 U.S.C. § 102/103

Claims 18-20 and 25-28 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,053,909 granted to Shadduck (hereinafter “Shadduck”).

The following is a quotation from the MPEP setting forth the three basic criteria that must be met to establish a *prima facie* case of obviousness:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2142, citing *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Shadduck discloses a low-power radio frequency (Rf) device for delivery of Rf energy in conjunction with optical radiation. The Rf device is said to induce thermal heating in tissue by creating ionic perturbations. The penetration depth of the Rf energy is increased when tissue is irradiated with a light beam having a wavelength that is

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absorbed by tissue. Shadduck teaches that irradiation of the tissue leads to a photosensitization in the form of enhanced conductance of the tissue to the fluence of Rf current.

Amended claims 18 and 25 recite an applicator having *at least one dielectric element disposed along at least a portion of the distal ends of the conducting elements ... to electrically insulate the cornea from the electrical conducting elements*. Shadduck fails to disclose such a dielectric element. In fact, Shadduck's device would be rendered inoperable by the positioning of a dielectric element between the conducting elements and the cornea because Shadduck requires the flow of electricity through corneal tissue. Shadduck adjusts the "bio-electrical characteristics of the targeted tissue" prior to application of Rf current by photosensitizing the tissue with light (col. 8, lines 20-22), and then "utilizes a high frequency alternating Rf current...that is adapted to flow between the paired bi-polar electrodes..." (col. 4, lines 46-49; FIGS. 2A-B and 8C). Thus, Shadduck expressly teaches away from the use of a dielectric element, and Applicant contends that the Examiner's use of Official Notice is inappropriate where - according to the teachings of Shadduck - it is not obvious "to dispose [an] electrically insulating coating on the forward end of an electrode to prevent direct contact between the body tissue and the conductor end so as to limit collateral tissue damage." (Office Action dated March 28, 2006 at page 4). We respectfully request withdraw of this rejection, or, in the event that the rejection is maintained, supporting evidence for the use of Official Notice as dictated by MPEP 2144.03(C).

Claims 20, 26 and 27 depend from claims 18 and 25, and benefit from arguments made above. Further, these claims include additional features that patentably distinguish over Shadduck. For example, claim 20 recites the dielectric element comprises anodized aluminum. Shadduck does not disclose *any* dielectric element, much less anodized aluminum. Claim 26 recites the control signals cause any of initiating a treatment protocol or terminating a treatment protocol. Shadduck states that "the surgeon can

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actuate the phased delivery of ionothermal energy" (col. 11, lines 14-15). Claim 27 recites the controller applies a stop signal to the generator when a treatment time associated with a treatment protocol exceeds a threshold defined for the treatment modality. Shadduck does not disclose a time threshold or a fail-safe mechanism for stopping the treatment protocol.

Reconsideration and allowance of claims 18, 20 and 25-27 is respectfully requested.

Claim 28 recites an applicator for performing thermokeratoplasty, comprising:

- (A) an electrically conducting tube extending from a proximal end to a distal end,
- (B) a conductive rod disposed within said tube and separated by a selected distance therefrom,
- (C) an insulator disposed between said conductive tube and said rod for providing electrical insulation therebetween,
- (D) wherein said conductive tube and said rod are configured to have a direct contact with corneal tissue at said distal end upon placement of the applicator on a subject's cornea.

Shadduck does not teach or suggest any mechanism like that recited in claim 28. Specifically, Shadduck does not disclose an electrically conducting tube having a conductive rod disposed therein and an insulator disposed between the tube and rod.

Reconsideration and allowance of claim 28 is respectfully requested.

Claims 21-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Shadduck in view of U.S. Patent No. 4,381,007 granted to Doss (hereinafter "Doss").

Doss discloses a multipolar probe that uses Rf energy delivered to a cornea by a plurality of tubular electrodes. A vacuum system moves a liquid electrically conductive coolant through or adjacent to at least one of the electrodes onto the cornea, then, from

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the cornea, through or adjacent to the other electrode. A damming device, or skirt, retains the coolant on the cornea.

Amended claim 21 recites an applicator for performing thermokeratoplasty, comprising:

- (A) an electrical conducting element comprising at least a pair of elongated conductors separated by a selected distance and extending from a proximal end to a distal end,
- (B) at least one dielectric element disposed along at least a portion of the distal ends of said conductors, said dielectric element being adapted for positioning on a portion of a patient's cornea to electrically insulate the cornea from the conductors,
- (C) an insulator disposed between said two conductors to provide electrical insulation therebetween, and
- (D) a vacuum source having at least one vacuum passage extending to said distal end and configured for applying suction to at least a portion of corneal tissue upon positioning of said applicator on the cornea.

As indicated above, Shadduck fails to disclose at least (B), a dielectric element disposed along at least a portion of the distal ends of the conductors and being adapted for positioning on a portion of a patient's cornea to electrically insulate the cornea from the conductors. Doss fails to remedy the deficiencies of Shadduck because Doss also fails to teach or suggest a dielectric element having such features.

Claims 22-24 depend from claim 21 and benefit from arguments made above. Reconsideration and allowance of claims 21-24 is respectfully requested.

Claims 2 and 4-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over AAPA in view of Doss and U.S. Patent No. 6,224,593 granted to Ryan et al. (hereinafter "Ryan").

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Claims 2 and 4-17 depend from independent claim 1 which, as described above, recites an applicator for performing thermokeratoplasty including at least one thermally conductive dielectric element disposed along at least a portion of the distal end of the electrically conductive element and being adapted for positioning on a portion of a patient's cornea to electrically insulate the cornea from the conductors. As indicated above, both AAPA and Doss fail to disclose a device having such features. Ryan fails to remedy the deficiencies of AAPA and Doss because Ryan merely discloses a method and apparatus for tissue and vessel sealing using microwave energy. Tissue is compressed between a microwave conductor and a tissue capture portion of an elongated member, which is suitable for laparoscopic surgeries. Ryan does not disclose a system that is suitable for thermokeratoplasty – much less a thermally conductive dielectric element disposed along at least a portion of the distal end of the electrically conductive element and being adapted for positioning on a portion of a patient's cornea to electrically insulate the cornea from the conductors, as required by claim 1.

Further, claims 2 and 4-17 contain elements that patentably distinguish over AAPA in view of Doss and Ryan. For example, claim 2 recites the dielectric element is formed of anodized aluminum. None of AAPA, Doss or Ryan disclose anodized aluminum. Claim 4 recites the dielectric element has a thermal conductivity in a range of about 0.1 W/(m °C) to about 200 W/(m °C). None of AAPA, Doss or Ryan disclose a dielectric element having a thermal conductivity in a range of about 0.1 W/(m °C) to about 200 W/(m °C). Claim 11 recites the metal forming the electrical conducting element can be any of stainless steel, steel, aluminum, brass, or copper. None of AAPA, Doss or Ryan disclose specific metals that are suitable for the fabrication of electrical conducting elements. Claim 12 recites a coating comprising alumina. Claim 13 recites the alumina coating comprises aluminum oxide particles in an aluminum matrix such that a concentration of the aluminum oxide particles varies from the proximal end to the distal end of the electrical conducting element. Claim 14 recites the concentration of the

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aluminum oxide particles reaches a maximum value in proximity of the distal end. None of AAPA, Doss or Ryan disclose alumina coatings; particularly, alumina coatings with graded concentration profiles.

Reconsideration and allowance of claims 2 and 4-17 is respectfully requested.

In view of the above Remarks, Applicant has addressed all issues raised in the Office Action dated March 28, 2006, and respectfully solicits a Notice of Allowance. Should any issues remain, the Examiner is encouraged to telephone Applicant's attorney, Curtis Vock at (720) 931-3011.

Authorization to charge fees associated with a two-month extension of time is submitted herewith. If any additional fee is deemed necessary in connection with this Response, please charge Deposit Account No. 12-0600.

Respectfully submitted,  
LATHROP & GAGE L.C.

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